UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

PAUL SCHILF and CYNTHIA SCHILF, as special administrators for the ESTATE OF PETER RAYMOND SCHILF, Deceased, and PAUL SCHILF and CYNTHIA SCHILF, individually,	*	CIV 07-4015
Plaintiffs,	*	MEMORANDUM OPINION AND ORDER GRANTING SUMMARY JUDGMENT
vs.	*	
ELI LILLY AND COMPANY and QUINTILES TRANSNATIONAL CORPORATION,	*	
Defendants.	*	

The Court has received the additional information from the parties in regard to Defendants' Motion for Summary Judgment on Plaintiffs' Failure to Warn Claims, doc. 123, and on Plaintiffs' Motion for Partial Summary Judgment on the Learned Intermediary Defense, doc. 126. For the following reasons, Defendants' motion will be granted and Plaintiffs' motion will be denied. In addition, the Court has determined that Plaintiffs cannot prevail on any theory, including deceit, because they cannot prove a failure to warn by Defendants caused their injuries. Plaintiffs' inability to prove causation is dispositive of all their remaining claims.

DISCUSSION

A. Learned Intermediary Doctrine

Defendants assert they are entitled to summary judgment on Plaintiffs' failure to warn claims based on the learned intermediary doctrine. Plaintiffs seek an order from this Court finding that South Dakota would not adopt the learned intermediary doctrine.

> The learned intermediary doctrine provides that a pharmaceutical manufacturer has a duty to warn a physician of the risks involved with a pharmaceutical, and the physician then acts as a 'learned intermediary' between the manufacturer and the physician's patient. Thus, a warning to the physician is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs.
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> This learned intermediary doctrine states that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs ans assess risks and benefits of a particular course of treatment. The learned intermediary doctrine has been adopted in most jurisdictions. . . .
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> .....as a learned intermediary, the physician has a duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use. Thus, the physician stands in the best position to balance the needs of patients against the risks and benefits of a particular drug or therapy, and the to supervise its use.
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> Under the learned intermediary doctrine, the manufacturer's failure to provide the physician with adequate warnings of the risks associated with a particular prescription product 'is not the proximate cause of the patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated. Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him.

Ehlis v. Shire Richwood, Inc. 367 F.3d 1013, 1016 (8th Cir. 2004)(citations omitted, punctuation altered). In *Ehlis*, the Eighth Circuit predicted the Supreme Court of North Dakota would adopt the learned intermediary doctrine. It cited three primary rationale for application of the rule: (1) medical ethics and practice dictate that the doctor must be an intervening and independent party between a patient and a drug manufacturer; (2) the information regarding risks is often too technical for a patient to make a reasonable choice on his/her own; and (3) it is virtually impossible in many cases for a manufacturer to directly warn each patient.

The South Dakota Supreme Court has never directly commented on the learned intermediary doctrine. Defendants rely on two federal cases which suggest the learned intermediary doctrine applies in South Dakota: *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969) and *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228 (D.S.D. 1983). In *Sterling*, the Eighth Circuit followed the Restatement (Second) 402A of Torts. It held that the district court did not err by finding that the drug company's actions in failing to instruct its "detail men at least, to warn the physicians on whom they regularly called of the dangers of which [the company] had learned, or in the exercise of reasonable care should have known." Sterling, 408 F.2d at 992. *McElhaney* was about the drug DES. Addressing the Restatement (Second) of Torts, comment k, which discusses prescription drugs, the district court stated, "In cases involving prescription drugs 'the manufacturer must warn the physician, not the patient.' The prescribing physician acts as a learned intermediary between the patient and the manufacturer. In this way, the consumer is able to determine the risks associated with the prescription drug." *McElhaney*, 575 F.Supp. at 231 (citations omitted).

Plaintiffs contend that the learned intermediary doctrine is "fundamentally inconsistent" with strict liability jurisprudence and urge this Court to predict South Dakota will not embrace this defense. Plaintiffs rely primarily on *Rimbert v. Eli Lilly*, 577 F.Supp.2d 1174 (D.N.M. 2008).

The Court finds the Eighth Circuit's reasoning in *Ehlis* instructive on this issue. In addition to finding the precedent overwhelming and the policy enunciated by the learned intermediary doctrine sound, the *Ehlis* Court reasoned that the North Dakota Supreme Court had adopted Section 402A of the Restatement (Second) of Torts, from which the learned intermediary doctrine evolves, and that because North Dakota had adopted other comments from section 402A it would likewise recognize the learned intermediary doctrine. The same can be said for South Dakota, as it has explicitly adopted the Restatement (Second) § 402A. *See Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909 (S.D. 1987). This Court concludes the South Dakota Supreme Court would adopt the learned intermediary doctrine. Thus, Plaintiffs' motion for summary judgment on the learned intermediary defense will be denied.

B. Adequacy of Warnings to Physician

Dr. Briggs read the FDA-approved prescribing information for Cymbalta before he prescribed Cymbalta for Peter Schilf. The "WARNINGS" section of the prescribing information contained a warning that patients with major depressive disorder may experience suicidality and that patients being treated with antidepressants should be observed for suicidality. The prescribing information also contained a statement in the "Other Adverse Events Observed During the Premarketing Evaluation of Duloxetine" that "completed suicide" and "suicide attempt" were observed events during clinical trials of Cymbalta. On October 15, 2004, based on its analysis of pooled data related to nine antidepressant drugs, not including Cymbalta, the FDA advised Lilly by letter that labeling changes to the Cymbalta label were warranted, to include a black box and other warnings regarding suicidality in children and adolescents using antidepressants.[1] The FDA also issued a press release on October 15, 2004, announcing that the FDA was directing manufacturers of antidepressant medications to add a "black box" warning to the prescribing information of all antidepressant medications stating that there is an increased risk of suicidal thoughts and behavior in children and adolescents being treated with antidepressant medications. The press release stated that Prozac is the only medication approved to treat depression in children and adolescents, but that the new warning does not prohibit the use of antidepressants in children and adolescents. "Rather, it warns of the risk of suicidality and encourages prescribers to balance this risk with clinical need."

Dr. Briggs diagnosed 16-year old Peter Schilf with depression on November 26, 2004 and provided him with samples of Cymbalta. When those samples were provided to Dr. Briggs' office, they contained the then-applicable package insert, which Dr. Briggs testified he read before prescribing Cymbalta. He also read the October 15, 2004 FDA press release. During the November 26, 2004 appointment, Dr. Briggs spoke with Peter Schilf and his mother, Cynthia, about antidepressant treatment and the potential risk of suicidality. Peter began taking Cymbalta. Dr.

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[1]Lilly was to submit proposed language within 30 days from the date of the letter, and that was done on November 15, 2004. On January 12, 2005, the FDA notified Lilly that the revised Cymbalta labeling was "approvable." It was finally approved with a modification by the FDA on January 26, and the final labeling revision was submitted to the FDA on February 4, 2005.

Briggs' December 17, 2004 record of the follow-up appointment with Peter states, in part: "Specifically asked him if he was having any problems and did address any suicidal ideations and again, as with the last visit, he denies any suicidal ideations and states that he would be willing to seek help should he have any concerns about hurting himself or others." Peter committed suicide on December 24, 2004. Dr. Briggs testified that the subsequent inclusion of a black box warning regarding suicide in the FDA-approved Cymbalta prescribing information has not changed his analysis of the benefits and risks of Cymbalta for teenage patients:

> Q: Let me ask you this: Have you made a conscious decision based on the black box warning not to use Cymbalta in a teenage patient under 18?
> N: No, no.

See Briggs' depo. at 111.

Defendants first argue that they are entitled to summary judgment because the Cymbalta package insert reviewed by Dr. Briggs contained warnings about suicidality which were adequate as a matter of law. Although suicidality is mentioned, the warnings provided by Lilly prior to the black box warnings do not convey a causal connection between taking Cymbalta and suicidality. For purposes of this motion for summary judgment, the Court will assume that the warnings prior to the black box warning were inadequate.

Defendants next assert that Dr. Briggs had independent knowledge of the risk that Cymbalta could cause suicide because he had read the October 15, 2004 FDA press release announcing that the FDA was directing manufacturers of antidepressant medications to add a "black box" warning to all antidepressants stating that there is an increased risk of suicidal thoughts and behavior in children and adolescents being treated with antidepressant medications. Plaintiffs admit that Dr. Briggs read the FDA announcement, but they believe Defendants should have told him something more. The Court has carefully reviewed the portions of Dr. Briggs' deposition provided by the parties.[2] Plaintiffs argue that Defendants should have gotten the word out about the upcoming black

[2]Until recently, the Court had only various excerpts from Dr. Briggs' deposition. On October 8, 2010, Plaintiffs filed a complete copy of the deposition which considerably aided the Court's ability to assess Dr. Briggs' testimony for purposes of this motion for summary judgment.

box warnings sooner, but Dr. Briggs read all about those warnings in the FDA press release prior to seeing Peter Schilf. Prior to prescribing Cymbalta to Peter, Dr. Briggs was aware of the same warnings that Plaintiffs now say Defendants should have given to prescribing physicians such as Dr. Briggs. Thus, a warning from Defendants would not have informed Dr. Briggs of anything he did not already know.

Finally, Defendants contend that their alleged failure to warn did not cause Peter's suicide because a different warning would not have changed Dr. Briggs' decision to prescribe Cymbalta for Peter, and thus Plaintiffs have failed to present evidence of causation. In support of this contention, Defendants principally rely on this quote from Dr. Briggs' deposition:

> Q: I believe you've already testified that, sitting here today, you still believe that your decision to prescribe Cymbalta for Peter Schilf was appropriate, correct?
>
> A: Yes.

See Briggs depo. at 112. Plaintiffs point out ambiguous testimony of Dr. Briggs in regard to other matters, but Dr. Briggs' testimony about whether he would prescribe Cymbalta for Peter Schilf given adequate warnings is straightforward. Plaintiffs did not discredit or call into question this testimony. The majority of cases governed by the learned intermediary doctrine turn on the prescribing physician's testimony as to what would have been done even if adequate warnings had been issued by the pharmaceutical company.[3] See Doc. 234, Defendants' Supplemental Memorandum (citing

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[3]In compliance with this Court's Order, doc. 225, Plaintiffs have just recently submitted additional evidence that a reasonable physician, adequately warned, would not have prescribed Cymbalta to Peter. *See* Plaintiffs' Response to Court's Order of 9/22/10. (Doc. 230.) It appears that only the Fifth Circuit has indicated that a plaintiff in some circumstances might be allowed to supplement the treating physician's testimony with objective evidence of how a reasonable physician would have responded to an adequate warning. *See Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) ("To satisfy the burden of establishing warning causation, a plaintiff may introduce either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded."); *Grenier v. Medical Engineering Corp.*, 243 F.3d 200, 205 n. 4 (5th Cir. 2001) (reaffirming holding in *Thomas* that plaintiff may introduce either objective evidence of how a reasonable physician would have responded to an adequate warning or subjective evidence of how the treating physician would have responded). The Court does not believe the South Dakota Supreme Court would adopt this minority view, particularly under the facts of this case where the treating physician's testimony

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cases and orders). Because Dr. Briggs' testimony that he still believes his decision to prescribe Cymbalta for Peter Schilf was appropriate is uncontradicted, there is not sufficient evidence of causation to allow the question to be submitted to the jury, and Defendants' motion for summary judgment on the failure to warn claims will be granted. *See, e.g., Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001) (applying Oklahoma law) ("To submit the case to a jury, [plaintiff] must either discredit the physicians' testimony or call into question the substance of the testimony, or otherwise demonstrate that the alleged failure to warn was the proximate cause of their injuries."); *Stafford v. Wyeth*, 411 F.Supp.2d 1318, 1322 (W.D. Okla. 2006) ("The question in the learned intermediary context is not what an objective physician would decide, but rather what plaintiff's doctor would determine.")

Plaintiffs argue that they are entitled to a rebuttable presumption, adopted by some states, that had there been an adequate warning, the doctor would have heeded it. Courts have based the adoption of this presumption on the following language in comment j of section 402A of the Restatement (Second) of Torts: "Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if followed, is not in defective condition, nor is it unreasonably dangerous." *See, e.g., Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) (explaining origin of presumption). Under the rebuttable presumption in the prescription drug context, once the plaintiff establishes that the manufacturer provided inadequate warnings, the burden shifts to the defendant to show that an adequate warning would not have affected the doctor's conduct in prescribing the drug. *See Thom*

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is unequivocal. Plaintiffs also cite *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377 (Okla. 1974), in support of the proposition that objective evidence is sufficient. *Cunningham* is distinguishable as it did not involve the learned intermediary doctrine. It was a mass vaccination setting where there was no true physician-intermediary relationship and the Oklahoma court held that the issue of proximate cause was for the jury to determine according to a reasonable person standard: would a reasonable person in the plaintiff's situation have refused the polio vaccine if adequately warned? In contrast, the learned intermediary doctrine applies in the present case and, therefore, Plaintiffs are required to show that a different warning would have changed Dr. Briggs' decision to prescribe Cymbalta to Peter.

v. Bristol-Myers Squib Co., 353 F.3d 848, 856 (10th Cir. 2003). If the defendant fails to make that showing, the presumption satisfies the plaintiff's burden of demonstrating that the inadequate warning was the proximate cause of the ingestion of the drug. *See id.* "But once the opposing party meets its burden to come forward with evidence rebutting the presumption, the presumption disappears." *Daniel v. Ben E. Keith Co.*, 97 F.3d 1329, 1332 (10th Cir. 1996). Thus, the rebuttable presumption is a burden-shifting device that makes it easier for a plaintiff to prove causation. Many courts have refused to apply the heeding presumption in prescription drug cases. *See, e.g., Thomas*, 949 F.2d at 812-14 (declining to create such a presumption under Mississippi law); *Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203, 214 (5th Cir. 2008) ("[T]he read-and-heed presumption does not apply to Texas cases involving learned intermediaries.")

Even if this Court were to predict that the South Dakota Supreme Court would adopt the heeding presumption and would apply it in a prescription drug case involving the learned intermediary doctrine, Defendants are entitled to summary judgment because they have rebutted the presumption with Dr. Briggs' unequivocal testimony that he still believes Cymbalta was appropriate for Peter Schilf. *See, e.g. Thom,* 353 F.3d at 856 ("the defendant can rebut the presumption through testimony that a different warning would not have made a difference in the actions of the physician"). Plaintiffs have not come forward with any evidence that a different warning may have altered Dr. Briggs' decision to prescribe Cymbalta to Peter.

Plaintiffs' deceit claim under SDCL 20-10-2(3) also must fail because it is completely subsumed by their failure to warn claims. In their Amended Complaint, Plaintiffs alleged that "suppression of information concerning completed suicides during the Cymbalta clinical trials is deceitful within the meaning of the statute." First Amended Complaint at ¶ 42. The Court is not aware of any evidence in the record to support this claim. In their motion for summary judgment on the deceit claim, Plaintiffs argued for summary judgment on a restated claim[4] that "Lilly was aware of the FDA's requirement of October 15, 2004, to provide factual information to both patients and

[4]Plaintiffs have not filed a formal motion to amend their deceit claim. The deadline to amend pleadings was December 7, 2007.

doctors about the risks of Cymbalta-induced suicidality and that Lilly purposefully chose not to disseminate any information about that risk before Dr. Briggs prescribed Cymbalta to Peter Schilf." (Doc. 126-2, p. 11.) This is no different than Plaintiffs' failure to warn claim because it is based solely on the contention that Defendants knew the risks of suicidality but failed to warn of the risks. *See, e.g., Bruske v. Hille*, 567 N.W.2d 872 (S.D. 1997) (physician's failure to warn patient of implant dangers, characterized by plaintiff as a deceit claim under SDCL 20-10-2(3), held to be a medical malpractice claim for negligent failure to warn and dismissed under the statute of limitations for malpractice actions). Because this particular deceit claim is a failure to warn claim Defendants also are entitled to summary judgment on the deceit claim. Accordingly,

IT IS ORDERED that Defendants' Motion for Summary Judgment on Plaintiffs' Failure to Warn Claims, doc. 123, is granted, and Defendants are also entitled to summary judgment on Plaintiffs' statutory deceit claim. Plaintiffs' Motion for Partial Summary Judgment on the Learned Intermediary Defense, doc. 126, is denied. These rulings render Plaintiffs' claim for punitive damages moot, and judgment will be entered in favor of Defendant on all claims.

Dated this 13th day of October, 2010.

BY THE COURT:

Lawrence L. Piersol
United States District Judge

ATTEST:
JOSEPH HAAS, CLERK

BY: Colleen Schutte
DEPUTY